

REMARKS

The issues outstanding the Office Action mailed July 11, 2007, are the rejections under 35 U.S.C. §112. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Rejections under 35 U.S.C. §112, second paragraph

Claim 29 has been rejected under 35 U.S.C. §112, second paragraph. While it is submitted that the claim satisfied the criteria for a "kit" or package claim, reciting structure such as "separate packages," the claim has been canceled for business reasons, in order to expedite prosecution. Withdrawal of this rejection is respectfully requested.

Claims 1-29 have been rejected under 35 U.S.C. §112, second paragraph. Reconsideration of this rejection is also respectfully requested. Various grammatical and typographic changes have been made, as requested at page 3 of the Office Action. It is thus submitted that the issues pertaining to the various terms, variables, etc. are moot.

With respect to claims 20-26, while it is not seen that the claims are not intended to encompass inhibition of *any* phosphodiesterase IV; this claim has also been canceled for business reasons in order to expedite prosecution. Withdrawal of these rejections is accordingly respectfully requested.

Claims 1-29 have been rejected under 35 U.S.C. §112, first paragraph. Reconsideration of this rejection is also respectfully requested. Inasmuch as this rejection pertains to the use of the term "derivatives," it is submitted moot by clarification of the present language. Withdrawal thereof is respectfully requested.

Rejections under 35 U.S.C. §112, first paragraph

Claims 20-26 have been rejected under 35 U.S.C. §112, first paragraph. It appears that the concern expressed in this rejection is that the wide variety of indications recited, in view of their breadth. In fact, such concern is misplaced. The heart of the remaining rejections, as stated in the Office Action, e.g., at page 6, appears to be the argument that the specification does not provide sufficient assurance that all indications susceptible to PDE IV inhibition are treatable by the herein claimed compounds. Applicants respectfully disagree

with this analysis. (It is noted, however, that to advance prosecution, and again for business reasons, the claims have been streamlined to recite a smaller group of indications.

First, at page 4, lines 17+, it is taught that the compounds of formula I inhibit PDE IV, and this statement is supported with a discussion of the methods used to determine this activity in the subject compounds. At page 5-7 of the specification, it is taught that the compounds show an antagonistic effect on the production of TNF, and thus are useful to treat allergic diseases, asthma, chronic bronchitis, atopic dermatitis, psoriasis or other skin diseases, inflammatory diseases, autoimmune diseases, sepsis, memory disorders, atherosclerosis, AIDS or myocardial disease. Clearly, this discussion, *without more* is sufficient to establish utility of the application for purposes of §112 of the statute, as it constitutes a scientifically supportable statement of utility which would be plausible to one of ordinary skill in the art.

It is well established that an unsupported suggestion that reactants within a class defined by claims in a typical method of use application would not work, or that such claims embrace inoperative members, insufficient basis alone for rejecting the claims. See *Ex parte Janin*, 209 U.S.P.Q. 761 (POBA 1979). In fact, it is clear that recitations in an Applicants' specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971).

The first paragraph of 35 U.S.C §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, supra. Applicants' specification clearly enables one to make and use the disclosed compounds in the claimed methods, as evidenced from the disclosure at page 5 - 7 setting forth pharmaceutical formulations and dosages and the examples which also detail the production of a pharmaceutical formulations.

On the one hand, it is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of utility in the specification and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. The "complex nature of the subject matter" which is "greatly exacerbated by the breadth of the claims" does not rise to the level of such reasons or evidence. As clearly stated in *Marzocchi*, mere *breadth* of the claims does not, without more, result in non-enablement. As the court stated in *Marzocchi*, supra (emphasis in original):

Turning specifically to the objections noted by the Board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that Applicants, when they included the disputed terms in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by Applicants that all of the 'considerable number of compounds' which are included in the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only relevant concern of the patent office under these circumstances should be over the *truth* of any such assertion. The first paragraph of §112 requires nothing more than *objective enablement*. How such a teaching is set forth, either by the use of illustrative examples or by broad term analogy, it is of no importance.

Thus, the concern expressed at pages 3 and 7 of the Office Action, apparently that the terms used in the claimed methods are broad, does not provide the reasons or evidence necessary by *Marzocchi* to pass beyond the necessity merely for objective enablement.

Further, in this regard, it is important to note, as a matter of law, that it is not necessary for Applicants' *method* claims to exclude inoperative embodiments, inasmuch as the claims are interpreted in light of the level of understanding one of ordinary skill in the art and, for methods, are interpreted to be *per se* functional. See *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976) and *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (CCPA 1974). These cases state that, for method claims, inoperative embodiments are not encompassed therein and the only questions is whether it would be undue experimentation for one of ordinary skill in the art to determine the scope of the claim. This issue is discussed more fully below. Moreover, screening protocols for determining the efficacy of the compounds in the various utilities are set forth in the specification where it is indicated that the details of using a given compound can be determined by routine testing using a known protocol which is correlated with human activity, see page 93, as well as pages 5-6.

It is submitted that the PTO has not furnished reasons or evidence why the objective enablement of the present specification fails. The discussion of *In re Wands*, taking up a substantial amount of the Office Action, does *not* provide the necessary reasons or evidence as to why utility is deficient, but instead is reached only in other circumstances, e.g., to assess "undue experimentation." However, since this analysis has been given considerable space in the Office Action, it will be addressed herein.

With respect to the nature of the invention, the *complexity* is in fact not supported by the breadth of the claim, as argued, for example, at page 8. In actuality, the nature of the invention is *not* complex, inasmuch as the use of PDE inhibitors to treat various indications is well established and would be well understood by one of skill in the art.

With respect to the breadth of the claims, it is important to note that a determination of undue experimentation must be considered on a *compound by compound* or *indication by indication* basis. The mere fact that a claim is broad does *not* mean that it is undue experimentation is required to determine enablement of the compounds therein, if it is not undue experimentation to determine enablement for *each* compound in the scope of the claim. See, for example, *In re Colianni*, 195 U.S.P.Q. 150 (CCPA 1977). One of ordinary skill in the art can easily determine, with the protocols given in the specification, whether a given compound has the utility stated. Thus, the mere fact that many compounds must be tested is not dispositive of lack of utility.

With respect to the guidance given by the instant specification, is submitted that the guidance is adequate, inasmuch as pharmaceutical formulation information is given, one of ordinary skill in the art can clearly prepare the compounds for administration, dosages are given and the pharmaceutical art is well developed and administration of a compound for a given indication is quite routine.

With respect to working examples, it is well established that working examples are *not* required to provide enablement. See, for example, *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970).

With respect to the state of the art, PDE inhibitors are well known to be implicated in signaling pathways which are instrumental in the etiology of disease.

In conclusion, it is submitted that the *Wands* factors clearly do not result in undue experimentation in order to determine whether a given indication and/or a compound is within the scope of the present claims. Thus, objective enablement is clearly present, and withdrawal of the rejection under 35 U.S.C §112 is respectfully requested.

The claims in the application are submitted to be in condition for allowance. However, if the examiner has any questions or comments, she is cordially invited to telephone the undersigned at the number below.

No fee is believed due with this response, however, the Commissioner is hereby

authorized to charge any fees associated with this response or credit any overpayment to
Deposit Account No. 13-3402.

Respectfully submitted,

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